

Art Unit: 1648

Nevertheless, with regard to an unpredictable field, this does not constitute an adequate disclosure. See *Fiers v. Revel* (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The result from in vitro experimentation cannot be extrapolated as a result in vivo. The applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Hence, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 6, 34, 35, 45-46, 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Binz et al. (FR 2 718 452).

22. Binz et al. disclose a RSV G protein polypeptide comprising entire amino acid sequence between the amino acid residues 130-230 of RSV G protein of subgroup A, or subgroup B, or bovine respiratory syncytial virus, wherein the polypeptide encoded by sequences disclosed in the specification sequences SEQ ID NO: 3, 4, 8, 14, 16, 18, 30, 36, 44, 50, 52, 61 to 66, 68 and 73. The polypeptide is also characterized with two cysteine residues missing at positions 73 and 86 mutations, such as SEQ ID NO: 3, 4, 14, 30, 44, 52, 61 and 68 (See claims 1-4 and Sequence disclosure of SEQ ID NO. 3, 4, 14, 30, 44, 52, 61 and 68). The claimed peptides are all immunogenic that are able to induce immune response and block the RSV infection (see entire document). Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claims 6, 11-13, 34, 35, 37, 39, and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binz et al. (FR 2 718 452) and Langedijk et al. (J. General Virol. 1996, Vol. 77, pp. 1249-1257).

25. Claimed invention is drawn to a synthetic peptide of amino acid residues 19-197 of RSV G protein, wherein more than one cysteine residues at positions of 173 and 176 or 182 and 186 may be blocked by forming an acetamidomethyl derivatives. The said polypeptide is able to inhibit the cytopathetic effect (CPE) of RSV infection in susceptible cells, and it can be used for treatment of RSV infection and diagnosis.

26. Binz et al. disclose a RSV G protein polypeptide comprising entire amino acid sequence between the amino acid residues 130-230 of RSV G protein of subgroup A, or subgroup B, or bovine respiratory syncytial virus, wherein the polypeptide encoded by sequences disclosed in the specification sequences SEQ ID NO: 3, 4, 8, 14, 16, 18, 30, 36, 44, 50, 52, 61 to 66, 68 and 73. The polypeptide is also characterized with two cysteine residues missing at positions 173 and 186 mutations, such as SEQ ID NO: 3, 4, 14, 30, 44, 52, 61 and 68 (See claims 1-4 and Sequence disclosure of SEQ ID NO. 3, 4, 14, 30, 44, 52, 61 and 68). The claimed peptides are all immunogenic that are able to induce immune response and block the RSV infection (see entire document). Binz et al. do not teach the peptide can be synthesized as acetamidomethyl peptide or replace some of the amino acid as its D-amino acid counterpart or labeled the peptide with detectable markers.

27. Langedijk et al. teach a method for synthesize the RSV G peptide from amino acid residues 149-197 with acetamidomethyl derivative at the C-terminal. They also disclosed that the immunogenicity of the derived peptide possesses the same immunogenicity as the originals.